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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,284

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Kazuyoshi Furusawa

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WASHINGTON, DC 20006-1021

EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

05/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,284	Applicant(s) FURUSAWA ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-13 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4-6, 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Amendment and Amended Claims filed on February 12, 2008 is acknowledged. Claims 3-13 remain pending. Claims 3 and 7-12 remain withdrawn. Claims 4-6 and 13 remain under examination. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates (US Patent 6,319,510) in view of Tapolsky et al. (US Patent 5,800,832).

Yates discloses a laminated gum pad for the delivery of medication to mucosal tissues. The gum pad can be used for a wide range of pharmaceutical agents (abstract). Yates further discloses the backing layer is a flexible thermoplastic sheet insoluble in saliva. Appropriate backing materials include ethyl cellulose and polyvinyl alcohol (column 7, lines 8-25). The reservoir layer may comprise a water-soluble particulate material or a water-soluble support matrix (column 7, line 66 to column 8, line 3). An excipient matrix or a hydrogel matrix serves to maintain the dispersion of active ingredients within the solution or suspension. Excipients matrixes can be formed from

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methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose or sodium carboxymethyl cellulose (column 8, lines 21-35). Suitable polymers for the hydrogel include polyvinyl alcohol, polyvinyl pyrrolidone, and polyethylene glycol (column 8, lines 35-45). Sweeteners such as sorbitol and buffers such as sodium hydroxide can be added (column 9, lines 25-29). Fentanyl citrate is disclosed as a suitable analgesic for transmucosal delivery (column 19, lines 5-28).

Yates does not disclose a synthetic water-soluble polymer compound as part of the back layer or the non-disintegrating layer and the disintegrating layer is colored to distinguish one layer from the other.

Tapolsky discloses a laminated water soluble, biodegradable delivery system for application to mucosal surfaces comprising an adhesive layer and a non-adhesive backing layer (abstract). The backing layer may comprise hydroxypropyl cellulose and hydroxypropylmethyl cellulose (column 3, lines 39-44).

The recitation of differences in color are regarded as an aesthetic change to the final product barring a showing a criticality to their function, and is therefore not given patentable weight. Matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art. (See MPEP 2144.04).

The recitation of the pH solution preparation is considered a product by process claim. Since the prior art discloses the same product to be used for the same purpose, the burden shifts to applicant to demonstrate a structure difference.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the water soluble polymers of Tapolsky into the backing layer of Yates since Tapolsky discloses the polymers are used in the backing layer of a laminated mucosal delivery system. The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). It would have been obvious to a person of ordinary skill to utilize the water soluble polymers of Tapolsky with the composition of Yates since Tapolsky discloses combinations of different polymers can be utilized to achieve preferred film forming capabilities, mechanical properties, and kinetics of dissolution (column 6, lines 50-55).

Response to Arguments

Applicant's arguments with respect to claims 4-6 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615